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10/588,428	08/04/2006	Hiroshi Nagai	SHOBA6.001APC	9228

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EXAMINER

PERREIRA, MELISSA JEAN

ART UNIT	PAPER NUMBER
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1618

NOTIFICATION DATE	DELIVERY MODE
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08/27/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No. 10/588,428	Applicant(s) NAGAI ET AL.	
	Examiner MELISSA PERREIRA	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 July 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2 and 5-7 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2 and 5-7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/31/09 has been entered.

Claims and Previous Rejection Status

2. Claims 1,2 and 5-7 are pending in the application.
3. The rejection of claims 1,2 and 5-7 under 35 U.S.C. 103(a) as being unpatentable over Zeyuan et al. (*J. Agric. Food Chem.* **1998**, 46, 3875-3878) and Xia (CN1435125; derwent Acc No 2004-023802) in view of Suzuki et al. (*J. Agric. Food Chem.* **2000**, 48, 5649-5653) and in further view of Iwasaki et al. (US 7,014,876B2) is maintained.
4. Applicant asserts that the Advisory action states that the evidence filed after the final action would not be entered. This is incorrect and the Advisory action clearly states that the proposed amendment will be entered and an explanation of how the new or amended claims was provided.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1,2 and 5-7 under 35 U.S.C. 103(a) as being unpatentable over Zeyuan et al. (*J. Agric. Food Chem.* **1998**, 46, 3875-3878) and Xia (CN1435125; derwent Acc No 2004-023802) in view of Suzuki et al. (*J. Agric. Food Chem.* **2000**, 48, 5649-5653) and in further view of Iwasaki et al. (US 7,014,876B2).

7. Zeyuan et al. (*J. Agric. Food Chem.* **1998**, 46, 3875-3878) discloses the method of reducing and examining blood triglyceride levels in a subject via the administration of black tea extracts/functional beverage (abstract; p3876, paragraph 2, results and discussion paragraph 1; p3877, paragraphs 2 and 3). The black tea extracts/functional beverage were prepared by boiling black tea for 5 min and subsequently filtering (p3876, Tea for Experiment and Sample Preparation).

8. Xia (CN1435125; derwent Acc No 2004-023802) discloses a health food prepared from oolong tea which is able to reduce triglycerides (abstract).

9. The references of Zeyuan et al. and Xia do not disclose the catechins of the instant claims, such as epigallocatechin-3-O-(3-O-methyl) gallate, etc. or that the catechin is derived from the tea leaves of the instant claims, such as Benihomare, etc.

10. Suzuki et al. (*J. Agric. Food Chem.* **2000**, 48, 5649-5653) discloses the oral administration of O-methylated catechin derivatives, such as (-)- epigallocatechin-3-O-

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(3-O-methyl) gallate (EGCG3"Me) to mice where the EGCG3"Me is extracted from the tea leaves of Tong ting oolong tea, Benihomare cultivar (black tea), etc. The O-methylated catechin derivative EGCG3"Me and (-)-epigallocatechin-3-O-gallate (EGCG) shows inhibition of type I and IV allergy (abstract; p5649, Introduction paragraphs 1 and 2; p5651, paragraphs 2 and 3). The tea extracts of the disclosure were prepared with hot water for 30 min and are then subsequently filtered (p5650, Materials and Animals). Suzuki et al. also discloses that the daily intake of tea drinks could have potential to prevent type IV allergy (abstract).

11. Zeyuan et al. and Xia teach that both black tea and oolong tea extracts containing catechins reduce blood triglyceride levels. Therefore, at the time of the invention it would have been obvious to one skilled in the art to use/try any catechins, such as O-methylated catechin derivative EGCG3"Me of Suzuki et al. obtained from black (Benihomare cultivar) or oolong teas (Tong ting oolong) for the method of reducing blood triglyceride levels of Zeyuan et al. and Xia. Suzuki et al. teaches that EGCG and EGCG3"Me are analogous and therefore, it is obvious to those skilled in the art to make known substitutions on compounds that are similar in structure and function to observe the effects on the function of such compounds and to use the observations/data to further manipulate a compound to generate the desired effect. Suzuki et al. and Zeyuan et al. have identical extraction processes for the black tea extracts/functional beverage and therefore it would have been obvious to one skilled in the art that the black tea extracts/functional beverage of Zeyuan et al. will comprise O-methylated catechin derivatives.

12. The references of Zeyuan et al. and Xia also do not disclose the catechin concentration of the instant claims.

13. Iwasaki et al. (US 7,014,876B2) discloses a healthy drink containing catechins which are extracted from tea, such as Oolong tea, black tea (column 1, lines 66+; column 2, lines 32-53; column 8, lines 41+). The concentrated tea extracts are prepared by treating tea leaves with hot water (column 8, lines 41+). The catechins found in Oolong tea are used in the healthy drink in an amount from 0.092 to 0.5 g per 100 ml (column 3, lines 16-20).

14. The disclosures of Suzuki et al., Zeyuan et al. and Iwasaki et al. are drawn to the same utility, such as a extracts of black and oolong tea containing catechins via adding hot water to tea leaves and therefore at the time of the invention it would have been obvious to one skilled in the art to use the catechin extract concentration of Iwasaki et al. for the method of reducing blood triglyceride levels of Zeyuan et al. as the black tea extract will advantageously improve the function of the liver (Iwasaki et al.).

Furthermore, it is obvious to vary and/or optimize the amount of (compound) provided in the composition, according to the guidance provided by (reference), to provide a composition having the desired properties such as the desired (ratios, concentrations, percentages, etc.). It is noted that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation." In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Response to Arguments

15. Applicant's arguments filed 7/31/09 have been fully considered but they are not persuasive.

16. Applicant asserts that the unexpected results obtained by applicant's invention were reported and that the specification discloses in example 3 that a test group given a beverage high in methyl catechins derived from "Benifuuki" tea had dramatically lowered triglyceride levels compared to a control group given a beverage low in methyl catechins derived from Barley tea.

17. First, objective evidence which must be factually supported by an appropriate affidavit or declaration to be of probative value includes evidence of unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. MPEP 716.01 (c) [R-2] I.

18. Second, the arguments of counsel cannot take the place of evidence in the record. In re Schulze, 346 F.2d 600, 602, 145 USPQ 716, 718 (CCPA 1965). Examples of attorney statements which are not evidence and which must be supported by an appropriate affidavit or declaration include statements regarding unexpected results, commercial success, solution of a long-felt need, inoperability of the prior art, invention before the date of the reference, and allegations that the author(s) of the prior art derived the disclosed subject matter from the applicant. MPEP 716.01 (c) [R-2] II.

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19. Further, Example 3 (table 2) found in applicant's specification provides a 28% (174 ± 82 to 125 ± 62) lowering of triglyceride values in the sixth week which is not an unexpected result in view of the reference of Zeyuan et al. which teaches that triglycerides were significantly reduces by 33.3% in green tea and 25.0% in black tea.

20. Applicant asserts that reference Document 1 (partial translation) reports similar results when a high methyl catechin tea, such as "Benifukki" is compared with a low methyl catechin tea, such as "Yabukita." Table 1 of reference Document 1 (partial translation) reports the results for a number of parameters in the two different groups, including "neutral fat," which is another term for triglycerides where a control group (not receiving an additive) and the "Yabukita" group had virtually the same neutral fat level at 61.2 mg/dL and the "Benifukki" group had a more than 20% reduction, at 50.0 mg/dL.

21. The reference Document 1 (partial translation) is not a part of the disclosure of the instant application and therefore cannot be used to support unexpected results.

22. Applicant asserts that teas high in methyl catechins have a significant TG-lowering effect, while teas low in methyl catechins have little effect on TG, Applicants identified the recited varieties of teas as those having high levels of methyl catechins.

23. Xia teaches that oolong tea is used to lower TG levels. Suzuki et al. teaches that O-methylated catechin derivatives, such as (-)-epigallocatechin-3-O-(3-O-methyl) gallate (EGCG3"Me) is extracted from the tea leaves of Tong ting oolong tea, Benihomare cultivar (black tea), etc. and that the O-methylated catechin derivative EGCG3"Me and (-)-epigallocatechin-3-O-gallate (EGCG) have analogous properties. Therefore it would have been obvious to one skilled in the art to substitute any of the

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catechin derivatives extracted from oolong tea or Benihomare for lowering TG levels as taught by Xia. The Benihomare of Suzuki et al. encompasses the Benihomare of the instant claims.

24. Applicant asserts that Zeyuan et al. shows that black tea has a relatively moderate level of TG-lowering effect, while the corresponding green tea had a significant greater TG-lowering effect. As described in Reference Document 2 (partial translation), the fermentation process involved in producing black tea from green tea substantially eliminates methyl catechins from the tea. Absent Applicant's discovery that teas high in methyl catechins produce an unexpectedly high level of TG-reduction, nothing in Zeyuan et al. reference would lead one having ordinary skill in the art to believe that the difference in TG-lowering effect results from differences in levels of methyl catechins. Thus, the difference in TG-lowering effects between the black tea and the green tea shown in the Zeyuan et al. reference supports the unexpected results observed by Applicants.

25. Zeyuan et al. teaches of the method of reducing and examining blood triglyceride levels in a subject via the administration of black tea extracts/functional beverage, Suzuki et al. teaches of O-methylated catechin derivatives, such as (-)-epigallocatechin-3-O-(3-O-methyl) gallate (EGCG3"Me) which are extracted from the tea leaves of Tong ting oolong tea, Benihomare cultivar (black tea), etc. and Iwasaki et al. teaches of the extraction from tea, such as Oolong tea, black tea where the catechins found in Oolong tea are used in the healthy drink in an amount from 0.092 to 0.5 g per 100 ml. Therefore it would have been obvious to one skilled in the art to

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utilize 0.092 to 0.5 g per 100 ml catechins found in Oolong tea, black tea, for example, EGCG3"Me of Suzuki et al. Also, it would have been obvious to one skilled in the art to utilize more Oolong tea, black tea, etc. leaves for extraction of catechins to provide for the desired concentration of the desired catechins.

26. Applicant asserts that Suzuki et al. discloses that a methylated catechin extract obtained from Benihomare and tong ting tea leaves has an anti-allergy effect. However, this reference does not teach or suggest that such an extract has any effect whatsoever on TG levels.

27. The reference of Suzuki et al. was not used to teach of the effect of methylated catechin on TG levels but was used to teach that EGCG3"Me is extracted from the tea leaves of Tong ting oolong tea, Benihomare cultivar (black tea), etc.

28. Zeyuan et al. teaches of the method of reducing and examining blood triglyceride levels in a subject via the administration of black tea extracts/functional beverage and Iwasaki et al. teaches of the extraction from tea, such as Oolong tea, black tea where the catechins found in Oolong tea are used in the healthy drink in an amount from 0.092 to 0.5 g per 100 ml. Therefore it would have been obvious to one skilled in the art to utilize 0.092 to 0.5 g per 100 ml catechins found in Oolong tea, black tea, for example, EGCG3"Me of Suzuki et al. The Benihomare of Suzuki et al. encompasses the Benihomare of the instant claims.

29. Applicant asserts that Iwasaki et al. teaches of an amount of catechin contained in oolong tea, but does not disclose anything about effective amounts of methylated catechins for reducing triglyceride levels. In addition, since the type and content of

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methyalted catechins is different for each variety of tea recited in claim 1, the effect of reducing triglyceride levels in a beverage in Iwasaki et al. is determined based on the type of tea leaf consumed. In fact, in view of the teaching of the enclosed reference, the oolong tea disclosed by Iwasaki et al. would not be expected to lower triglyceride levels since it contains only trace amounts of catechins.

30. The reference of Iwasaki et al. was not used to teach of effective amounts of methyalted catechins for reducing triglyceride levels but was used to teach that catechins found in Oolong tea are used in the healthy drink in an amount from 0.092 to 0.5 g per 100 ml. Suzuki et al. teaches that EGCG3"Me is extracted from the tea leaves of Tong ting oolong tea, Benihomare cultivar (black tea), etc. Therefore, it would have been obvious to one skilled in the art to utilize catechins, such as EGCG3"Me extracted from the tea leaves of Tong ting oolong tea, Benihomare cultivar in a healthy drink in an amount from 0.092 to 0.5 g per 100 ml. It would have been obvious to one skilled in the art to utilize more Oolong tea, black tea leaves for extraction of catechins to provide for the desired concentration of the desired catechins. Also, the Benihomare of Suzuki et al. encompasses the Benihomare of the instant claims.

31. Applicant asserts that one having ordinary skill in the art would not have any reason to select the particular varieties recited in the present claims out of all the many varieties of tea, because such a person would not know to select the varieties that have high levels of methyl catechins.

32. Zeyuan et al. and Xia teach of the use of black tea extracts/functional beverage and health food prepared from oolong tea, respectively, to reduce triglycerides. Suzuki

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et al. teaches that EGCG3"Me is extracted from the tea leaves of Tong ting oolong tea, Benihomare cultivar (black tea), etc. Therefore it would have been obvious to one skilled in the art to utilize EGCG3"Me extracted from the tea leaves of Tong ting oolong tea, Benihomare cultivar (black tea), etc. for the method of reducing triglycerides. Also, the Benihomare of Suzuki et al. encompasses the Benihomare of the instant claims and therefore one skilled in the art would know how to select a tea having high levels of methyl catechins.

Conclusion

33. No claims are allowed at this time.

34. This is a continuation of applicant's earlier Application No. 10/588,428. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA PERREIRA whose telephone number is (571)272-1354. The examiner can normally be reached on 9am-5pm M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

/Melissa Perreira/
Examiner, Art Unit 1618